CLAIMS

What is claimed is:

1. A system for creating and using product data comprising:

at least one adverse event database for storing adverse event data associated with a commercially available product;

a processor for accessing and analyzing data from said at least one adverse event database to assist in identifying new adverse events associated with the product and to assist in identifying at least one new use for the product responsive to identification of at least one new adverse event associated with the product;

an adverse event information storage device for storing at least new adverse event data identified by said processor;

a user computer for making requests for adverse event information to and for receiving adverse event information from said processor;

a user interface for interfacing said processor and said user computer.

2. The system of claim 1 wherein said processor, said adverse event information storage device and said user interface reside on a server.

3. The system of claim 2 wherein said at least one adverse event database resides on said server.

4. The system of claim 2 wherein said at least one adverse event database does not reside on said server.

5. The system of claim 4 further comprising a shadow storage device for storing adverse event data associated with a product that is retrieved from said at least one adverse event database.

6. The system of claim 5 wherein said shadow storage device resides on said server.

7. The system of claim 1 wherein said adverse event information storage device additionally stores previously known adverse event data associated with the product.

8. The system of claim 1 wherein the product is a medical product.

9. The system of claim 8 wherein the medical product is a generic drug.

10. The system of claim 1 wherein the product is a non-medical product.

11. The system of claim 1 wherein said product data is proprietary.

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12. A method for creating and using product data, said method comprising the steps of:

accessing at least one adverse event data source that stores adverse event data associated with a commercially available product;

analyzing said adverse event data to identify new adverse events associated with the product;

creating at least one adverse event information database, said creating comprising analyzing data from said at least one adverse event data source to identify at least one new use for the product responsive to identification of at least one new adverse event associated with the product, said creating further comprising storing adverse event information, said adverse event information including said at least one new use; and

commercializing adverse event information stored at said at least one adverse event information database.

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13. The method of claim 12 further comprising creating sale or licensing documents incorporating said adverse event information stored at said at least one an adverse event database.

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14. The method of claim 12 further comprising generating printed product warning information derived from said adverse event information stored at said at least one an adverse event database.

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15. The method of claim 12 wherein said step of generating printed product warning information is performed by a server which supports operation of said method.

16. The method of claim 12 wherein said step of generating printed product warning information is performed by a third party purchaser or third party licensee that purchases or licenses said adverse event information from an owner of said adverse event information.

17. The method of claim 12 wherein said step of commercializing comprises selling or leasing of said adverse event information.

18. The method of claim 12 wherein said step of commercializing comprises manufacturing and selling products incorporating said adverse event information.

19. The method of claim 12 further comprising creating intellectual property, sale or licensing documents incorporating information from said at least one adverse event information database.

20. The method of claim 19 wherein said intellectual property documents comprise patent applications.

21. The method of claim 19 wherein said intellectual property documents comprise copyright applications.

22. The method of claim 12 wherein said at least one an adverse event information database additionally stores previously known adverse event data associated with the product.

23. The method of claim 12 wherein said at least one adverse event data source stores adverse event data in populations of at least about 5000 persons.

24. The method of claim 12 wherein said at least one an adverse event information database additionally stores post-exposure adverse event product data in selected time increments ranging from less than one hour to more than ten years.

25. The method of claim 12 wherein said at least one an adverse event information database additionally stores risk versus benefit information regarding new adverse event data associated with the product.

26. The method of claim 12 wherein said at least one an adverse event information database additionally stores comparative adverse event data for target groups receiving the product and control groups not receiving the product.

27. The method of claim 12 wherein the product is a medical product.

28. The method of claim 27 wherein the medical product is a generic drug.

29. The method of claim 12 wherein the product is a non-medical product.

30. The method of claim 12 wherein said product data is proprietary.

31. The method of claim 12 wherein said at least one new use is a restrictive use restricting use of said product in at least one population group observed in said creating step to be at high risk of adverse events associated with use of the product.

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32. The method of claim 12 wherein said at least one new use is an expansive use expanding use of said product in at least one population group observed in said creating step to be at low risk of adverse events associated with use of the product.

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33. The method of claim 12 further comprising conducting at least one prospective study to verify a newly discovered adverse event.

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34. The method of claim 12 wherein said adverse event information further comprises information on at least one of a user's sex, weight, age, race, genetic characteristics, medical condition, pregnancy status, allergies, use of medicines and use of medical devices.

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35. The method of claim 12 wherein said adverse event information further comprises information on amount or duration of exposure by a user to the product.

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36. The method of claim 12 wherein said adverse event information database further stores information on at least one adverse event including death, hospitalization, missed work, medical costs, abnormal lab results and surgeries.

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37. The method of claim 12 wherein said adverse event information database further stores information including rates of adverse events occurring in population ratios as frequently as 1:100 up to about 1:10,000,000.

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38. The method of claim 12 wherein said adverse event information database further stores information on cumulative adverse events.

42. The method of claim 15 wherein said adverse event information database further stores information with the interaction of a plurality different products.

43. The method of claim 15 wherein said at least one adverse event data source comprise a plurality of adverse event data sources.

47. A method of establishing at least one new use for a commercially available product, said method comprising the steps of:

comparing raw adverse event data associated with a product with previously known adverse event data associated with the product;

observing in said raw adverse event data at least one new adverse event associated with the product; and

identifying at least one new use for the product responsive to observing said at least one new adverse event associated with the product.

48. The method of claim 47 further comprising generating printed product warning information containing notification of said new adverse event data associated with the product.

49. The method of claim 48 further comprising providing said printed product warning information in connection with product packaging.

50. The method of claim 48 wherein the product is a medical product.

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45. The method of claim 44 wherein the medical product is a generic drug.

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46. The method of claim 41 wherein the product is a non-medical product.

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47. The method of claim 41 wherein said at least one new use is proprietary.

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48. The method of claim 41 wherein said at least one new use is a restrictive use restricting use of said product in at least one population group observed in said creating step to be at high risk of adverse events associated with use of the product.

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49. The method of claim 41 wherein said at least one new use is an expansive use expanding use of said product in at least one population group observed in said creating step to be at low risk of adverse events associated with use of the product.

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50. The method of claim 41 further comprising conducting at least one prospective study to verify a newly discovered adverse event.

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51. The method of claim 41 wherein said adverse event information further comprises information on at least one of a user's sex, weight, age, race, genetic characteristics, medical condition, pregnancy status, allergies, use of medicines and use of medical devices.

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52. The method of claim 41 wherein at least one of said raw adverse event data and said previously known adverse event data is stored on at least one computerized database.

62. A computer for managing product data comprising:

at least one database storing adverse event data associated with a commercially available product;

a processor for accessing and analyzing data from said at least one database to assist in identifying new adverse events associated with the product and assist in identifying at least one new use for the product responsive to identification of at least one new adverse event associated with the product; and

an adverse event information storage device for storing adverse event information including said at least one new adverse event associated with the product and said at least one new use for the product identified by said processor.

63. The computer of claim 62 further comprising a user interface for interfacing said processor with a user computer.

64. The computer of claim 62 wherein said at least one adverse event database resides on said computer.

65. The computer of claim 62 wherein said at least one adverse event database does not reside on said computer.

66. The computer of claim 65 further comprising a shadow storage device for storing adverse event data associated with the product that is retrieved from said at least one adverse event database.

67. The computer of claim 66 wherein said shadow storage device resides on said server.

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59. The computer of claim 53 wherein said adverse event information storage device additionally stores previously known adverse event data associated with the product.

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60. The computer of claim 53 wherein the product is a medical product.

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61. The computer of claim 60 wherein the medical product is a generic drug.

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62. The computer of claim 53 wherein the product is a non-medical product.

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63. The computer of claim 53 wherein said product data is proprietary.

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64. A proprietary product created using the system of claim 1.

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65. A proprietary product created using the method of claim 12.

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66. A proprietary product created using the method of claim 41.

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67. A proprietary product created using the computer of claim 53.

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68. A proprietary kit containing the product and labeling notifying a user of at least one new adverse event for the product, the kit being created using the system of claim 1.

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69. A proprietary kit containing the product and labeling notifying a user of at least one new adverse event for the product, the kit being created using the method of claim 12.

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70. A proprietary kit containing the product and labeling notifying a user of at least one new adverse event for the product, the kit being created using the method of claim 47.

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71. A proprietary kit containing the product and labeling notifying a user of at least one new adverse event for the product, the kit being created using the computer of claim 62.

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72. A method of using the proprietary kit of claim 68 in accordance with a proprietary new use for a commercially available product.

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73. A method of using the proprietary kit of claim 69 in accordance with a proprietary new use for a commercially available product.

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74. A method of using the proprietary kit of claim 70 in accordance with a proprietary new use for a commercially available product.

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75. A method of using the proprietary kit of claim 71 in accordance with a proprietary new use for a commercially available product.